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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/580,403 | 08/18/2006 | Hiroshi Kubo | Q94683 | 2089 |

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| EXAMINER | |
|---|---|
| VAKILI, ZOHREH | |
| ART UNIT | PAPER NUMBER |
| 1614 | |
| MAIL DATE | DELIVERY MODE |
| 10/30/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/580,403 | KUBO ET AL. | |
| | Examiner | Art Unit | |
| | ZOHREH VAKILI | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *10,11 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/31/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

**Claims 10, 11, and 22 are presented for examination.**

The Finality of the action, mailed April 29, 2009 is hereby withdrawn.

Claims amendment filed on August 31, 2009 has been entered into the present application.

Applicant's Amendment filed August 31, 2009 has been received and entered into the present application. Claims 10, 11, and 22 are pending and are herein examined on the merits.

Applicant's arguments and remarks, filed August 31, 2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

***Claim Rejections - 35 USC § 102***

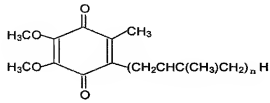
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

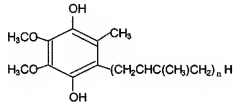
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 03032968.

WO 03032968 disclose the following formula (1):



n expressing an integer of 1-12 among a formula, and/or a following formula (2):



An antioxidant constituent for oxidant stress reduction which uses as an active principle coenzyme Q (see page 1 of translated document).

WO 03032968 further teaches the antioxidation constituent which can reduce oxidant stress in the living body. The influence of the oxidant stress to hepatopathy, diabetes mellitus, and liver cirrhosis is known. The usefulness of the anti-oxidant considered to have the ability to cancel oxidant stress (see page 2, 1st paragraph of translated document).

Once liver cells are protected from damage by the anti-oxidant coenzyme Q it is inherent that GPT or GOT activities are reduced in blood. The opposite is also seen when there is damage to liver cells GPT or GOT activities in blood would increase.

Therefore, by introducing antioxidant to reduce the increase of GPT or GOT activity in blood is an inherent property.

***Claim Rejections - 35 USC § 103***

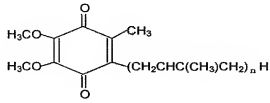
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

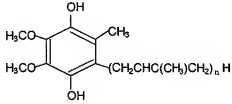
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03032968 and in view of Sokol (US Pat. No. 6069167).

WO 03032968 disclose the following formula (1):




n expressing an integer of 1-12 among a formula, and/or a following formula (2):




An antioxidant constituent for oxidant stress reduction which uses as an active principle coenzyme Q (see page 1 of translated document).

WO 03032968 further teaches the antioxidation constituent which can reduce oxidant stress in the living body. The influence of the oxidant stress to hepatopathy, diabetes mellitus, and liver cirrhosis is known. The usefulness of the anti-oxidant considered to have the ability to cancel oxidant stress (see page 2, 1st paragraph of translated document).

Sokol provides formulations and methods for preventing and treating liver injury and fibrosis that occur in cholestatic liver disease and related liver diseases. This is done by administering a composition that includes selected antioxidant compounds (see col. 1, lines 8-12). It is preferred that the ingredients described herein be admixed and administered together in a solution to be taken orally once or twice per day (see

col. 6, lines 42-44). The method of preventing and treating liver damage caused by cholestasis as previously described wherein the Vitamin E is provided in an amount of between about 25 and about 100 IU/kg/day; the beta-carotene in an amount of between about 0.5 to 5.0 mg/kg/day; and the **selenium** about 1 to 5 micrograms/kg/day (col. 4, lines 5-9). Other possible components of the antioxidant formulation of the instant invention can be coenzyme Q (ubiquinone) and its derivatives or analogs at doses between about 0.5 mg/kg/day and 10 mg/kg/day (col. 7, lines 66-67 and col. 8, lines 1-2). As evidenced by Tao et al. that disclose a method comprising a biologically effective amount of the bioactive agent; wherein the bioactive agent comprises a **Coenzyme Q in either its reduced form (ubiquinone) or oxidized form (ubiquinol)** (see claim 14). The composition of claim 1, further comprising an anti-oxidant (see claim 17). Wherein the anti-oxidant comprises one or more of Vitamin E (tocopherol), Vitamin K, Copper, Zinc, **Selenium, and Coenzyme Q** (see claim 18). Therefore, the oxidized form of coenzyme q can be replaced by reduced form in Sokol and also as taught by the WO 03032968 both oxidized and reduced from of coenzyme Q is used.

It would have been obvious to have combined the teachings of the above references to provide a method for protecting liver functions of a mammal comprising coenzyme Q and selenium.

One would have been motivated to create such a method because WO 03032968 teach the formula of oaxidized and reduced coenzyme Q to be used in treatment of liver diseases. Sokol provides the same method in addition with selenium

to treat liver disease in mammals. Therefore, one of ordinary skill in the art would have been motivated to use the combination of these antioxidants taught by the above references to develop a method for protecting liver function.

Applicant has argued that the above references do not teach the reduction of an increase in GPT or GOT activity in blood. The references teach treatment of liver diseases. As evidenced by Koike et al. to test for liver functions triglyceride contents in the blood, liver, and perirenal adipose tissues were determined by a Triglyceride Test. A total cholesterol quantity in the liver was determined by a Cholesterol E. GPT (glutamic oxaloacetic transaminase) activity and GPT (glutamic pyruvic transaminase) activity in the blood were determined by separating sera (see paragraph 0035). It is understood from the results the triglyceride content in perirenal adipose tissues, the triglyceride content in the liver, the total cholesterol content in the liver, the serum transaminase levels (GOT, GPT) and the triglyceride content in the blood can also be reduced (see paragraph 0037). Therefore, once a compound is used in treatment of liver diseases will naturally effect the level of GOT and GPT.

Finally, one would have a reasonable expectation of success given that the above references provide a detailed blueprint for making the formulation, and the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention of claims 10, 11, and 22 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Applicant's remarks and arguments submitted on 8/31/2009 have been fully and carefully considered in their entirety, but fail to be persuasive.

***Conclusion***

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614 October 20, 2009

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614